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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,928	01/22/2004	Michael P. McCarthy	469201-716 5745	
Raymond J. Lillie, Esq. c/o Carella, Byrne, Bain, Gilfillan, Cecchi, Stewart & Olstein 6 Becker Farm Road Roseland, NJ 07068			EXAMINER SALIMI, ALI REZA	
			1648	
			DATE MAILED: 09/27/2005	

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)			
Office Action Summary		10/762,928	MCCARTHY ET AL.			
		Examiner	Art Unit			
		A R. Salimi	1648			
Period fo	The MAILING DATE of this communication app or Reply	pears on the cover sheet with the	correspondence address			
WHIC - Exter after - If NO - Failu Any r	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DATE of time may be available under the provisions of 37 CFR 1.1.5 SIX (6) MONTHS from the mailing date of this communication. Period for reply is specified above, the maximum statutory period ver to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATIO 36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE.	N. mely filed the mailing date of this communication. ED (35 U.S.C. § 133).			
Status						
1)⊠	Responsive to communication(s) filed on <u>09 Fe</u>	ebruary 2005				
•	This action is FINAL . 2b)⊠ This action is non-final.					
,	, —					
٠,٣	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Dispositi	on of Claims					
	4) Claim(s) 1-7 is/are pending in the application.					
	4a) Of the above claim(s) is/are withdrawn from consideration.					
•	5) Claim(s) is/are allowed.					
·	☐ Claim(s) 1-7 is/are rejected.					
•	7) Claim(s) is/are objected to. B) Claim(s) are subject to restriction and/or election requirement.					
ا ا(٥	Claim(s) are subject to restriction and/o	r election requirement.				
Applicati	on Papers					
9)🖂 🤄	The specification is objected to by the Examine	r.				
10)⊠ The drawing(s) filed on <u>22 January 2004</u> is/are: a)⊠ accepted or b)⊡ objected to by the Examiner.						
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
	Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).					
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority u	ınder 35 U.S.C. § 119					
·	Acknowledgment is made of a claim for foreign ☐ All b) ☐ Some * c) ☐ None of:	priority under 35 U.S.C. § 119(a)-(d) or (f).			
	1. Certified copies of the priority documents have been received.					
	 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). 					
* S	See the attached detailed Office action for a list	of the certified copies not receive	ed.			
Attachmen	t(s)					
	e of References Cited (PTO-892)	4) Interview Summary	(PTO-413)			
2) Notic	e of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail D	ate			
	nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) r No(s)/Mail Date <u>3/3/04</u> .	5)	Patent Application (PTO-152) etter.			

DETAILED ACTION

Claims 1-7 are pending. Submitted Information Disclosure Statement (I.D.S) is noted.

Sequence Requirements

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. For example, see page 45 of the disclosure.

Full compliance with the sequence rules is required in response to this Office Action. A complete response to this office action should include both compliance with the sequence rules and a response to the Office Action set forth below. Failure to fully comply with **both** these requirements in the time period set forth in this office action will be held non-responsive.

Claim Rejections - 35 USC § 112

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the steps and conditions that reassemble the disassembled papillomavirus VLPs are missing. Precise conditions that would lead to reassembly in part (ii) should be provided. Removal of reducing agent is needed as an essential step for reassembly to take place. This affects the dependent claims 2-7.

Claim 7 recites the limitation "wherein <u>reassembly</u>.....reducing agent" in lines 1 to 2. There is insufficient antecedent basis for this limitation in the claim. Claim 5 speaks of conditions of disassembly of VLPs, no reassembly is discussed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 108-109, 111-119 of copending Application No. 09/457,594. Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap in scope. In addition, the subject matter of the claims are so closely related that would incorporate overlap species and/or claim 1 is so broadly drafted that would incorporate any and all species that may or may not be present in ,594 application.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,416,945 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap in scope. In addition, the subject matter of the claims are so closely related that would incorporate overlap species and/or claim 1 is so broadly drafted that would incorporate any and all species that may or may not be present in ,945 patent.

Claims 1-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,261,765 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap in scope. In addition, the subject matter of the claims are so closely related that would incorporate overlap species and/or claim 1 is so broadly drafted that would incorporate any and all species that may or may not be present in ,765 patent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Salunke et al (Cell, 1986, Vol. 46, pages 895-904). The broad limitations of the claim is clearly anticipated by the teaching of Salunke et al. The cited reference taught purification of disassembled polyomavirus

wherein the disassembled VLPs were reassembled (see page 903, left column, 1st full paragraph and 2nd paragraph, also see page 897, right column first full paragraph).

Allowable Subject Matter

Claims 2-7 are objected to as being dependent upon a rejected base claim.

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. R. Salimi

9/22/2005

PRIMARY EXAMINER

Application No.: 16/762,928
NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING
NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s)

1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
7. Other:
Applicant Must Provide:
An <u>initial</u> or substitute computer readable form (CRF) copy of the "Sequence Listing".
An <u>initial</u> or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).
or questions regarding compliance to these requirements, please contact:
For Rules Interpretation, call (703) 308-4216
or CRF Submission Help, call (703) 308-4212
For Patentin software help, call (703) 308-6856

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE